

From: Rio, Ellie [/O=MCKESSON/OU=NORTH AMERICA/CN=RECIPIENTS/CN=47425493]
Sent: 11/1/2013 5:01:11 AM
To: Taylor, Kim M [kim.taylor@mckesson.com]; Morrissey, Dave [dave.morrissey@mckesson.com]; Ferreira, Brian [brian.ferreira@mckesson.com]; Moore, Andrew [andrew.moore@mckesson.com]; Zaske, Jeff [jeff.zaske@mckesson.com]; Stern, John [john.stern@mckesson.com]; Montreuil, Daniel [daniel.montreuil@mckesson.com]; Naughton, Chris [chris.naughton@mckesson.com]; Snider, Blaine [blaine.snider@mckesson.com]; Offerman, Kim [kim.offeran@mckesson.com]; Fraser, Kirk [kirk.fraser@mckesson.com]; Piazza, Joe [joe.piazza@mckesson.com]; Oriente, Michael [michael.oriente@mckesson.com]; Lumpkin, Joe [joe.lumpkin@mckesson.com]; Bindert, Mike [michael.bindert@mckesson.com]; Bresnahan, Leigh [leigh.bresnahan@mckesson.com]; Mallory, Sidney [sidney.mallory@mckesson.com]; Jasek, Paul [paul.jasek@mckesson.com]; Schwichow, Drew [drew.schwichow@mckesson.com]; Weissel, Andrew [andy.weissel@mckesson.com]; Foster, Timothy [timothy.foster@mckesson.com]; Ha, Samuel [samuel.ha@mckesson.com]; Bandish, Stacey [stacey.bandish@mckesson.com]; 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#ServiceFirst Westlake-ISM Team [#servicefirstwestlake-ismteam@mckesson.com]
CC: Reference Documents: NE Suspicious Order Monitoring Awareness Training
Subject:

As indicated, this meeting will be conducted via WebEx (link below). However, attached please find a number of additional documents that we are providing for your reference and internal use only.

Thanks

Ellie Rio

Director, Business Initiatives
Customer Operations

928-707-2323 cellphone

McKesson Corporation
US Pharmaceutical
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Phoenix, AZ 85012
www.mckesson.com

-----Original Appointment-----

From: Rio, Ellie

Sent: Thursday, October 24, 2013 6:29 AM

To: Taylor, Kim M; Ursini, Brenda; Morrissey, Dave; Ferreira, Brian; Moore, Andrew; Zaske, Jeff; Stern, John; Montreuil, Daniel; Naughton, Chris; Snider, Blaine; Offerman, Kim; Fraser, Kirk; Piazza, Joe; Oriente, Michael; Lumpkin, Joe; Bindert, Mike; Bresnahan, Leigh; Mallory, Sidney; Jasek, Paul; Schwichow, Drew; Weissel, Andrew; Foster, Timothy; Ha, Samuel; Bandish, Stacey; Graziano, David; Hungridge, Robert; Bescript Jr, John; Shapiro, Paul; Sharma, Chetan; Smith, David (Retail Sales Manager); App, Daniel; Gonzalez, Christopher; Mastrianni, Ben; Mathurin, Bill; Rose, Tim; Varden, Tom; Warren, Tom; Bradley, Jeff; Corrigan, Samantha; Dahl, Jennifer; Morse, Shaun; Niland, Barry; Ahearn, Tom; Binsse, Alexandra; Grayson, Kimberly; Knott, Jason; Kuczynski, John; Brian, Scott; Calendrillo, Michele; Feliciano, Ruben; Goodrich, Maureen; Smith, Denisha; Turiano, Bob; Mathurin, Michele; Otto, Thomas; Lutwin, Joe; McAndrews, Mark; Bellora, Scott; Reghetti, Lisa; Hess, Tom; Mezhir, John; 'Paul.Shapiro@McKesson.com'; Menchise, Jessica; Adam, Garry; Finnegan Dorothy, Diane; Rios, NancyD; McMorrow, Nichole; Jackson, Benata; Woods, Michael; Grover, William; Thompson, Wendy; Cella, Christopher; Anderson, Perry; White, Robert (Retail Sales Manager)

Cc: Miller, ScottM; Longwell, Sharon; Fay, Richard; Thomas, Jon; Flach, Paul; McKeon, Rich; Brown, Lori; Eastham, Mark; Harrison, Jennifer; Hamlin, Tena; Butler, Scott; Stubbs, Andrew; White, Lori; Gibson, David; Kubena, Jackie; Maestas, Aaron; Petrus, Susan; Bell, Melinda; Ray, Brooke; Lytton, James; Rose, Scott; Nichols, Sherie; Stanger, Rob; Stites, Stacey; Zaben, Jay; Hou, Stella; Cearley, Trevor; Phillips, Joshua; Martin, Richard; Loudenslager, Doug; Davis, Eric; #ServiceFirst Westlake-ISM Team

Subject: Suspicious Order Monitoring Awareness Training

When: Friday, November 01, 2013 7:00 AM-8:00 AM (GMT-07:00) Arizona.

Where: 1-888-334-2993 participant code: 873924 WebEx Details Below

Sent on behalf of Don Walker::

Team:

As you are aware, we are in the process of implementing an enhanced **Suspicious Ordering Monitoring Program**. As a pharmaceutical distributor, McKesson has a responsibility to ensure pharmaceutical controlled substances are not diverted for non-medical or other illegal purposes. To that end, we are further enhancing our controlled substances distribution policies and procedures.

On **November 1st**, we invite you to participate in a critical Sales Awareness training that will provide you with important information regarding these program enhancements. Please refer to webcast details provided below.

Event address for attendees: <https://mck.webex.com/mck/onstage/g.php?t=a&d=749182528>

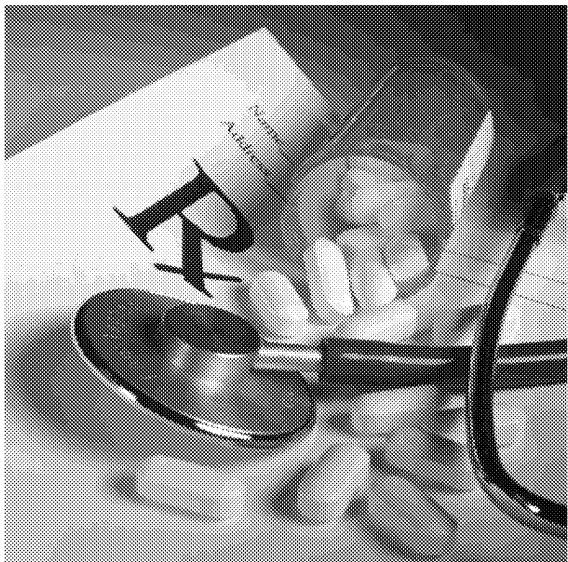
Date and time: Friday, November 1, 2013 7:00 am

Pacific Daylight Time (San Francisco, GMT-07:00)

Duration: 1 hour

Dial in: 1-888-334-2993
Participant passcode: 873924

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Controlled Substance Compliance Program

November 1, 2013



Controlled Substance Compliance Program

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Background

- As a *DEA registrant*, each *Distribution Center* has regulatory responsibilities under the controlled substances laws.
- The regulations create a closed system of distribution and require a program to detect and prevent diversion of controlled substances by customers.
- We are rolling our existing controlled substance SOPs under an umbrella program as well as:
 - Adding a more formal governance structure
 - Elevating the importance of training and education

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Controlled Substance Compliance Program

Governance

Licensing

DC
Manufacturing
Customer

Record-keeping & Reporting

ARCOS
Theft
Loss

Controlled Substance Monitoring Program

- Customer Diligence
- Suspicious Order Monitoring

Security

Training & Education

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Controlled Substance Monitoring Program

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Significant Enhancements to CSMP

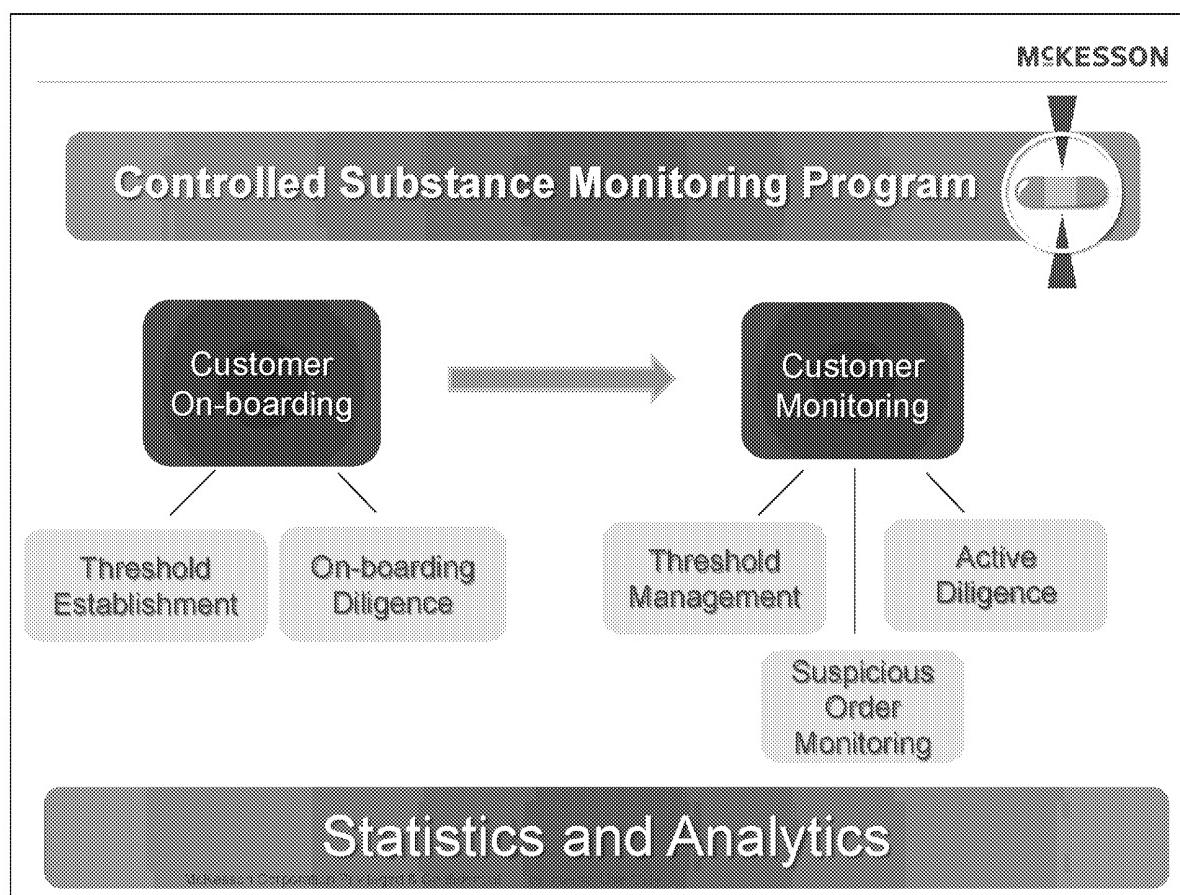
Core Elements remain the same

- Customer Diligence
- Monitoring Against Suspicious Orders
- Decisions to sell controlled substances to customers

Key Enhancements underway

- More sophisticated data analysis used to:
 - Evaluate a customer against average customer purchasing profiles
 - Set thresholds for a customer
- More rigorous process for Threshold Change Requests
 - Changes are the exception, not rule
- Reinforcement of decision making within the Regulatory Affairs team
 - Additional oversight by second level Managers & cross-functional Governance Committee
- Corresponding investments to expand the Regulatory Affairs team

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Roles & Responsibilities

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Regulatory

- Overall management and administration of the CSMP program
- Conduct CSMP reviews of customers, including site visits
- Provide CSMP program information to Sales, Ops & Customers
- Oversight and audit of recordkeeping and reporting

Operations

- Conduct site visits and complete questionnaires for new customers
- Ensure accurate recordkeeping and reporting
 - ARCOS
 - Theft & Loss

Sales

- Interface between customer & Regulatory, including:
 - Completing Threshold Change Request Form based on customer request
 - Collecting script data when requested by DRA
 - Providing routine sales call observations to DRA
 - Communicating decisions to customers

Compliance to SOPs

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To: Sales Associates
What: Script & Talking Points Regarding RETAIL Controlled Substance Threshold Inquiries or Threshold Changes Being Made

Background

- As a pharmaceutical distributor, McKesson has the responsibility for helping to prevent pharmaceutical controlled substances from being diverted for nonmedical or other illegal purposes.
- Distributors are obligated to design and operate a system to detect and report suspicious orders. Suspicious orders include orders of unusual size, orders deviating substantially from normal patterns, and orders of unusual frequency.

If a customer calls with questions regarding an OMIT for controlled substances or about changes to our program, the following information is being provided.

- *The script is intended for verbal discussions with customers only; do NOT share this document with customers in written form.*
- **Customer calls because they received a controlled substance OMIT and they want to find out if they have reached their monthly threshold.**
 - If you are getting an OMIT, it means you've reached your monthly threshold.
- **Customer asks if we have changed their threshold.**
 - As a part of our controlled substance monitoring program, we have and will continue to conduct reviews and make programmatic changes based on statistical, regional, geographic purchasing profiles.
 - We have implemented a more sophisticated data analyses process to set thresholds for our customers. We are analyzing our own sales data to identify average pharmacy purchase profiles on a regional basis. This means that thresholds are being established based on our customers, our distribution data and the geographical markets we serve.
 - I do not know if your specific threshold has been changed, but I do know that we are not communicating thresholds or providing threshold warning reports.
 - The statistical analysis is structured to be dynamic, not static, as purchasing patterns and diversion trends change.
- **Customer requests to know their exact monthly threshold limit.**
 - We are not communicating specific thresholds or providing threshold warning reports. We believe this is a better practice. Thresholds are not intended to allow customers to manage against a number. We strongly believe that customers should exercise their corresponding responsibility¹ one prescription at a time. Prescription drug abuse is an epidemic, and we all must do our part to fight this nationwide problem.

¹ See customer education material referenced in resource section at end of this document for details regarding a pharmacy's corresponding responsibility

- **Customer requests a threshold increase.**

- We are not routinely making any customer -requested threshold changes. As indicated, thresholds are being set based on data analysis done on our customers, our distribution data and the geographic markets that we serve.

[If customer indicates need for an increase]

- If you believe you do not fit the average profile or have a circumstance for threshold consideration, I will need you to provide me factual details regarding your pharmacy business model, specific circumstances, and supporting evidence of your need for this specific request. Please submit this information to me and I will forward it for regulatory compliance review. Please be aware, however, that we may require additional information from you in order to complete our review of this request.

Resources:

- For additional information on industry trends and background materials, please reference the following resources that can be found on **FETCH**:
<https://www.gosavo.com/fetch/CustomPage/View.aspx?id=1950281&srlid=21968783&srsp=rm=False&sritidx=0&srpgidx=0&srpgsz=1>
- **Controlled Substances Sales Overview, August 2013**
- **McKesson customer educational piece, August 2013**
- **Other controlled substance reference materials:**
 - *Code of federal regulation that pertains to a pharmacist's corresponding responsibility*
 - *DEA presentation*
 - *NSDU – 2011 National Survey on Drug Abuse and Health: Mental Heath Findings*
 - *NIH- revised Dec 2012 - National Institute on Drug Abuse Report*
 - *AZ Bests practices*

Websites:

- www.drugabuse.gov
- <http://www.deadiversion.usdoj.gov/>
- www.whitehouse.gov/ondcp
- www.cdc.gov
- http://www.samhsa.gov/data/NSDUH/2k11MH_FindingsandDetTables/Index.aspx
- www.DEAChronicles.com
- www.GetSmartAboutDrugs.com
- www.JustThinkTwice.com

To: Customer-Facing Sales Support -ServiceFirst
 What: SOP, Script & Talking Points Regarding RETAIL Controlled Substance Threshold Inquiries or Threshold Changes Being Made

Background

- As a pharmaceutical distributor, McKesson has the responsibility for helping to prevent pharmaceutical controlled substances from being diverted for nonmedical or other illegal purposes.
- Distributors are obligated to design and operate a system to detect and report suspicious orders. Suspicious orders include orders of unusual size, orders deviating substantially from normal patterns, and orders of unusual frequency.

If a customer calls with questions regarding an OMIT for controlled substances or about changes to our program, the following information is being provided.

- The script is intended for verbal discussions with customers only; do NOT share this document with customers in written form.*
- Customer calls because they received a controlled substance OMIT and they want to find out if they have reached their monthly threshold.**
 - If you are getting an OMIT, it means that you've reached your monthly threshold.

The following Controlled Substance Monitoring Program message can appear on a customer's invoice:

Omit Code	Invoice Message	Definition
V	Monthly regulatory maximum exceeded	Customer has reached their monthly limit

- Customer asks if we have changed their threshold**
 - As a part of our controlled substance monitoring program, we have and will continue to conduct reviews and make programmatic changes based on statistical, regional, geographic purchasing profiles. I do not know if your specific threshold has been changed, but I do know that we are not communicating thresholds or providing threshold warning reports. If you have any additional questions, I'd be happy to have your sales representative contact you.
- Customer requests to know their exact monthly threshold limit.**
 - We are not communicating thresholds or providing threshold warning reports. If you have any additional questions, I'd be happy to have your sales representative contact you.
- Customer requests a threshold increase.**
 - Any inquiries regarding threshold changes need to be directed to your sales representative. If you have any additional questions, I'd be happy to have your sales representative contact you.

Threshold Change Form**Request Date:**

Customer Name: _____	Customer Contact Name: _____
Address: _____	Title: _____
_____	Phone: _____
_____	Customer Account Number: _____
DEA number: _____	_____

Economost Number, Description or Base Code**Dosage amount requested:**

1. CS requested: _____ +/- amount
2. CS requested: _____ +/- amount
3. CS requested: _____ +/- amount
4. CS requested: _____ +/- amount
5. CS requested: _____ +/- amount

Customer-provided reason for requested change (BE SPECIFIC):**Submitted by:**

Name/Title: _____ Date: _____

DRA Approval _____ Denial _____ by: _____

DRA Name: _____ Date: _____

Sr. DRA / SVP Distribution Operations (if required) Approval _____ Denial _____ by: _____

Name: _____ Date: _____

Administrative note: All Threshold Change Request Forms (both accepted and denied) are to be maintained in the customer's Due Diligence File.

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November 1, 2013

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Controlled Substance Monitoring Program

McKesson Sales Procedures:

Request for Pharmacy Script Data File or Data Report

Effective Date: November 1, 2013

Use the following process when requesting pharmacy script data information for internal use in conjunction with McKesson's Controlled Substance Monitoring Program. This practice has been designed to help prepare the customer's data for analysis.

As of today, McKesson has two methods to facilitate the script data request process. The process is based on the customer's pharmacy system. If the customer uses a validated pharmacy system, customers will send the file to Customer Care's ServiceFirst team; however if the customer uses a non-validated pharmacy system, the script data report should be sent to his/her sales representative.

As of November 1, 2013, these are the validated systems: MPS-EnterpriseRX, MPS-Pharmaserv, MPS-Pharmacy RX, RX30, ComputerRX, BestRX, Eterby, Opus, PSI, Cost Effective, Digital Rx, Foundation and HCC.

All others pharmacy systems are non-validated at this time.

Validated Pharmacy Systems Process

Following are the applicable steps for validated pharmacy systems.

- Share the appropriate customer document when requesting a pharmacy script data file for McKesson validated pharmacy systems.
- The customer must provide script data (previous 3 full months, excluding current month) to McKesson as an .xls or .csv file as generated from their pharmacy management system and include total prescriptions filled excluding non-Rx.
- Direct the customer to send the file to Customer Care's ServiceFirst team at SF_CSCP@McKesson.com and copy you, their sales representative.
- ServiceFirst will format the data for analysis. All files received by 2:00 p.m. CST will be returned to the DRA the same day.
- Files will be reviewed by the DRA to determine next steps.

Non-Validated Pharmacy Systems Process

Following are the applicable steps for non-validated pharmacy systems.

- Share the appropriate customer document when requesting a pharmacy script data report for McKesson non-validated pharmacy systems.
- The customer must provide a script data report (previous 3 full months, excluding current month) to McKesson as shown in the report request.
- Direct the customer to email the report to their sales representative.
- The sales representative should forward the file to the DRA for review.

For questions or "How To" instructions, contact ServiceFirst at SF_CSCP@McKesson.com or Brooke Ray at 817-258-7140.

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**McKesson's Controlled Substance Monitoring Program: Request for Pharmacy Script Data File
For McKesson Validated Pharmacy Systems ***

In connection with a review of your account, McKesson is requesting additional information regarding the prescriptions filled and dispensed by your pharmacy. This information is being collected for internal use in connection with McKesson's Controlled Substance Monitoring Program. McKesson is not requesting any patient or doctor specific information or protected health information (see below for further explanation).

Upon receipt of this request, please provide information for the previous 3 full months (excluding current month's data).

- Information should be provided in the form of a file (.xls; .csv) generated from your pharmacy management system and cover total prescriptions filled excluding non-Rx.
- Once the data is collected, send the file to SF_CSCP@McKesson.com and your sales representative.

The file should include the following data:

- Pharmacy's name
- Pharmacy's DEA number
- The date that the file was generated
- The date range for which the file was generated
- Total number of prescriptions (controlled, non-controlled, excluding non-RX) dispensed during previous 3 full months
- Total number of dosage units dispensed for prescriptions (controlled, non-controlled, excluding non-RX) during previous 3 full months
- NDC number for the above items dispensed
- Item description for the above items dispensed

McKesson is not requesting any patient or doctor specific information or protected health information. Below are examples of information that should not be included in the script data report. This list is not intended to be comprehensive.

1. Prescription numbers;
2. Patient name;
3. Patient address or phone numbers;
4. Dates directly related to an individual, including birth date, date prescription filled, date prescription dispensed;
5. Social Security numbers;
6. Driver license numbers or other government issued identification numbers;
7. Medical record numbers;
8. Health plan beneficiary numbers; or
9. Physician information.

Disclaimer: The above is not intended to form a determination of whether the information constitutes protected health information as defined under federal or state privacy law

***Validated systems as of November 1, 2013: MPS-EnterpriseRX, MPS-Pharmaserv, MPS-Pharmacy RX, RX30, ComputerRX, BestRX, Eterby, Opus, PSI, Cost Effective, Digital Rx, Foundation and HCC.**

Please contact SF_CSCP@McKesson.com or your sales representative for instructions on how to obtain needed files for McKesson validated pharmacy systems.

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1

McKesson's Controlled Substance Monitoring Program: Request for Pharmacy Script Data Report

In connection with a review of your account, McKesson is requesting additional information regarding the prescriptions filled and dispensed by your pharmacy. This information is being collected for internal use in connection with McKesson's Controlled Substance Monitoring Program. McKesson is not requesting any patient or doctor specific information or protected health information. (See attachment at the end of this document for further explanation.)

Upon receipt of this request, please provide information for the previous 3 full months (excluding current month's data). Information should be provided in the form of a report generated from your pharmacy management system and cover total prescriptions filled.

The report should include the following data: (dates are for example only)

- Pharmacy's name (1)
- Pharmacy's DEA number (2)
- The date that the report was generated (3)
- The date range that the report was generated for: (4)
- Total number of prescriptions (controlled and non-controlled) dispensed during previous 3 full months (5)
- Total number of dosage units dispensed for prescriptions (controlled and non-controlled) during previous 3 full months (6)
- Total number of prescriptions dispensed for all controlled substances during previous 3 full months (7)
- Total number of dosage units dispensed for all controlled substances during previous 3 full months (8)
- Total number of prescriptions AND total number of dosage units (including brand and generic for the base items including combination products) indicated below (9) :

REQUIRED

AS SELECTED

Oxycodone

- Oxycodone 30mg
- Remaining Oxycodone

Amphetamine

Buprenorphine

Carisoprodol

Clonazepam

Hydrocodone

- Hydrocodone 10mg
- Remaining Hydrocodone

Oxymorphone

Phentermine

Hydromorphone

Methadone

Morphine

Alprazolam

Separate each NDC # and provide the total RXs and total doses for each, as demonstrated in the example below (Details above can be identified by matching the number indicators on the report).

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NOTE: THE RESULTS AND INFORMATION BELOW ARE PURELY FOR DEMONSTRATION PURPOSES.

123 MAIN STREET PHARMACY (1) DEA #: XX1234567 (2) DATE: JULY 15, 2013 (3)

REPORTING PERIOD: April 1, 2013 – June 30, 2013 (4)

Total # of ALL Prescriptions Dispensed: 24,220 (5)

Total Doses of ALL Rx's Dispensed: 519,050 (6)

Total # of ALL Controlled Substance Rx's Dispensed: 2,450 (7)

Total Doses of ALL Controlled Substance Rx's Dispensed: 87,300 (8)

Dispensing Data for Requested Ingredients: (9)

NDC	Drug Name	Total # of Doses (Qtv /Units dispensed)
00054-0404-50	MORPHINE SULF 100 MG/5ML	9,720
46987-0322-11	KADIAN ER 20 MG CAPSULE	1,360
00228-3505-11	MORPHINE SULFATE ER 60MG	620
42858-0802-01	MORPHINE SULF ER 30 MG	1,950
Total # of Rx's containing MORPHINE: 30	Total # of Doses containing MORPHINE:	2,570
00406-8530-01	OXYCODONE HCL 30 MG TAB	3,105
Total # of Rx's containing OXY 30mg: 75	Total # of Doses containing OXY 30mg:	3,105
59011-0410-10	OXYCONTIN 10 MG TABLET	1,700
59011-0440-10	OXYCONTIN 40MG TABLET	2,225
60951-0712-70	ENDOCET 10/325 MG TAB	3,050
Total # of Rx's containing (all other) OXY: 90	Total # of Doses containing (all other)OXY:	6,975
67253-0903-50	ALPRAZOLAM 2 MG TABLET	2,200
67253-0901-50	ALPRAZOLAM 0.5 MG TAB	1,310
Total # of Rx's containing ALPRAZOLAM: 19	Total # of Doses containing ALPRAZOLAM:	3,510
00591-2612-05	HYDROCOD/ACET 10/325MG	1,002
Total # of Rx's containing HYDRO 10mg: 11	Total # of Doses containing HYDRO 10mg:	1,002
00591-0349-05	HYDROCODONE/APAP 5/500MG	4,275
00406-0357-05	HYDROCODONE-APAP 5-500MG	1,100
Total # of Rx's containing (all other) HYDRO: 60	Total # of Doses containing (all other)HYDRO: 5,375	

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**ATTACHMENT TO
REQUEST FOR PHARMACY SCRIPT DATA**

McKesson is not requesting any patient or doctor specific information or protected health information. Below are examples of information that should not be included in the script data report. This list is not intended to be comprehensive.

1. Prescription numbers;
2. Patient name;
3. Patient address or phone numbers;
4. Dates directly related to an individual, including birth date, date prescription filled, date prescription dispensed;
5. Social Security numbers;
6. Driver license numbers or other government issued identification numbers;
7. Medical record numbers;
8. Health plan beneficiary numbers; or
9. Physician information.

Disclaimer: The above is not intended to constitute a determination of whether the information constitutes protected health information as defined under federal or state privacy laws.